REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office action dated June 24, 2003 are respectfully requested. Applicants petition the Commissioner for a 2-month extension of time. A separate petition accompanies this amendment.

I. Amendments

Claim 26 is amended to recite "α-linolenic fatty acid" as described in line 1 of claim 26.

Claim 34 is amended to correct a typographical error.

No new subject matter has been added by way of these amendments.

II. Rejection under 35 U.S.C. §112, second paragraph

Claim 26 was rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Specifically, the Examiner objected to the language "and alpha-linolenic fatty" as allegedly vague and indefinite.

Applicants have amended claim 26 in accord with the Examiner's kind suggestion to recite "and α-linolenic fatty acid".

Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112, second paragraph.

III. Rejections under 35 U.S.C. §103

Claims 26, 34, 38, and 42 were rejected under 35 U.S.C. §103 as allegedly obvious over Leach (U.S. Patent No. 5,612,074).

Claims 27, 31, 35, 39, and 43 were rejected under 35 U.S.C. §103 as allegedly obvious over Leach in view of Erasmus *et al.* (U.S. Patent No. 5,656,312) and Hunter *et al.* (U.S. Patent No. 4,863,753).

Claims 28, 30, 32, 36, 40, and 44 were rejected under 35 U.S.C. §103 as allegedly obvious over Leach and further view of Igarashi (U.S. Patent No. 6,159,507).

This rejection is respectfully traversed for the following reason.

A. The Invention

The present invention relates to a composition, an edible oil, and a dietary supplement consisting essentially of linoleic fatty acid (n-6, 18:2) and α-linolenic fatty (n-3, 18:3) in a linoleic to α-linolenic weight ratio of 0.05-7.5 and which contains flaxseed oil. In the attached 37 C.F.R. §1.132 Declaration of Dr. Insu P. Lee, Dr. Lee states that the "basic and novel characteristic" of the invention includes the following two elements (i) a linoleic fatty acid/α-linolenic fatty acid weight ratio of 0.05-7.5; and (ii) flaxseed oil (see Point 5 of Dr. Lee's Declaration). With respect to element (i), Dr. Lee notes in Point 8 that at a weight ratio of linoleic fatty acid to α-linolenic fatty acid of 0.05 to 7.5, DHA is synthesized most efficiently, particularly in the brain. As further described in Point 8 of Dr. Lee's Declaration, addition of ingredients that alter the linoleic fatty acid to α-linolenic fatty acid weight ratio outside of this weight ratio fail to produce the increase in cognitive and learning faculty and in the memory.

B. The Cited Art

LEACH A detailed summary of the Leach reference was provided in the amendment submitted February 18, 2003. A brief summary is provided here for convenience.

Leach describes a food bar having a ratio of dry ingredients to liquid ingredients of 3:1 (Col. 2, lines 65-67). Leach further teaches that considering both the oil seeds of the mixture of dry ingredients and the vegetable oil of the mixture of liquid ingredients, polyunsaturated linoleic acid is present in the food bar in a ratio of about 3:1 by weight to super-unsaturated alpha-linolenic acid (Col. 5, lines 12-16).

Thus, Leach teaches that the linoleic/linolenic ratio of the oil seeds in the dry ingredients and the vegetable oil in the liquid ingredients should be in a 3:1 ratio. This is in contradistinction to a teaching of an end product having a linoleic/linolenic ratio of 3:1, since it is clear that the resulting foodbar in Leach will not have a linoleic/linolenic ratio of 3:1.

ERASMUS *ET AL.* describe a composition and method for preparing a food supplement. The supplement includes at least 70% by weight of an oil seed constituent which may be flax seed or perilla seed.

HUNTER *ET AL.* disclose a peanut butter with reduced calories through reduction of the amount of peanut oil and total oil. This is achieved by replacement of at least a portion of the peanut oil with triglycerides containing medium chain fatty acids. The remaining fatty acids may be long chain fatty acids such as linoleic and linolenic acid. It is preferred that peanut butter contain from about 5% to about 25% linoleic acid and up to about 15% linolenic acid. The peanut butter further generally contains up to about 5% of a stabilizer consisting of an oil such as rapeseed oil. It is disclosed that linolenic oil is found in linseed oil and perilla oil.

IGARASHI describes a "balance modifier" that can be added to food in order to adjust the *in vivo* ratio of omega-6 unsaturated fatty acids to omega-3 unsaturated fatty acids.

C. Analysis

As stated in M.P.E.P. § 2143, "to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references (or references when combined) must teach or suggest all the claim limitations."

1. Rejection over Leach

As discussed above, the claimed invention includes a composition, edible oil, dietary supplement, or food consisting essentially of linoleic fatty acid and α–linolenic fatty acid in a weight ratio of 0.05-7.5 and containing flaxseed oil. As noted in Point 8 and 9 of Dr. Lee's Declaration, addition of an amount of a linolenic

and/or α–linolenic acid containing ingredient that moves the linoleic/α–linolenic weight ratio outside of 0.05-7.5 is excluded.

According to MPEP § 2111.03, "[t]he transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s)' of the claimed invention." Additionally, "[i]f an applicant contends that additional steps or materials in the prior art are excluded by the recitation of 'consisting essentially of,' applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention." In the claims of the instant application the "basic and novel characteristic" of the invention is the weight ratio of α–linolenic fatty acid to α–linolenic fatty acid in the range of 0.05-7.5.

The Examiner's attention is directed to Point 8 of Dr. Lee's Declaration where it is discussed that at the weight ratio of linoleic fatty acid to α-linolenic fatty acid of 0.05 to 7.5, DHA (docosahexaenoic acid) is synthesized most efficiently, particularly in the brain. As further detailed in Point 8 of Dr. Lee's Declaration, addition of ingredients that alter the linoleic fatty acid to α-linolenic fatty acid weight ratio outside of this weight ratio fail to produce the increase in cognitive and learning faculty and in the memory.

As discussed in Point 7 of Dr. Lee's Declaration, Leach discloses a food bar with a ratio of linoleic fatty acid to α-linolenic fatty acid of 3:1 only for the oil seeds of the mixture of dry ingredients and the vegetable oil of the liquid ingredients. Leach discloses numerous ingredients in the food bar that materially effect the ratio of linoleic/α–linolenic fatty acid. For example, soy, oatmeal, cornmeal, wheat germ, barley, rye, date, almond, sesame seed, sunflower seed, Fruitein and coriander seed are each disclosed as ingredients for the food bar. Each of these is a source of linoleic and/or α–linolenic fatty acid[1] and addition of any one or more would materially alter the ratio of these fatty acids. In summary, the food bar taught in Leach contains numerous ingredients that provide linoleic and/or α–linolenic fatty acid.

[1]see table provided in the amendment submitted February 18, 2003.

As described in Point 7 of Dr. Lee's Declaration, nowhere does Leach teach that the final food bar composition must contain a linoleic and/or α–linolenic acid weight ratio of between 0.05-7.5. In fact, no consideration of the final linoleic and/or α–linolenic acid weight of the Leach food bar is given. The teaching in Leach with respect to linoleic/α–linolenic acid ratio is limited to a teaching of a 3:1 ratio for the oil seeds of the dry ingredients and the vegetable oil of the liquid ingredients (see Col. 3, lines 41-47 and Col. 5, lines 12-16 which are set forth above). Leach fails to consider the effect of any of the other linoleic and/or α–linolenic acid-contributing ingredients on the final linoleic and/or α–linolenic acid ratio in the food bar.

This point is clearly illustrated by considering the first exemplary food bar disclosed in Leach on Col. 5, line 23 et seq. As described in the amendment submitted February 18, 2003, when all the ingredients are considered, the linoleic fatty acid to α–linolenic fatty acid weight ratio of the final food bar is at least 8.6, which is well outside of the 0.05-7.5 range recited in the claims of the present invention.

Thus, Leach fails to teach either a composition, edible oil, dietary supplement, or food consisting essentially of linoleic fatty acid and α–linolenic fatty acid in a weight ratio, and containing flaxseed oil, or the specified weight ratio of 0.05-7.5.

2. Rejection over Leach in view of Erasmus et al. and Hunter et al.

As noted above, Leach fails to teach a composition consisting essentially of linoleic fatty acid and α–linolenic fatty acid in a weight ratio of 0.05-7.5 and containing flaxseed oil.

The combined and/or separate teachings of Erasmus *et al.* and Hunter *et al.* do not make up for this deficiency.

3. Rejection over Leach in view of Igarashi

As noted above, Leach fails to teach a composition consisting essentially of linoleic fatty acid and α–linolenic fatty acid in a weight ratio of 0.05-7.5 and

containing flaxseed oil. The combined and/or separate teaching of Igarashi *et al.* do not make up for this deficiency.

Since the combined and/or separate teachings of the cited references fail to teach a composition that consists essentially of linoleic fatty acid and α–linolenic fatty acid in a weight ratio of 0.05-7.5, the standard for obviousness has not been satisfied and withdrawal of the rejection under 35 U.S.C. §103 is respectfully requested.

IV. Conclusion

In view of the foregoing, Applicants submit that the claims pending in the application are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4410.

Respectfully submitted,

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Date: Nov. 24, 2003

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